

**Final Rule**

LSA Document #11-458(F)

**DIGEST**

Amends [410 IAC 1-6-3](#) through [410 IAC 1-6-7](#), [410 IAC 1-7-7](#), [410 IAC 1-7-8](#), and [410 IAC 1-7-10](#) through [410 IAC 1-7-16](#) to clarify the definitions, to clarify the information and counseling given to a pregnant patient, to clarify reasons for not offering a human immunodeficiency virus test, to add the rapid test, to remove documentation that must be noted in the pregnant patient's medical record, to add information that must be included on the confidential part of each birth certificate, to clarify provider's responsibilities to a pregnant patient, and to update references to the Indiana Code. Adds [410 IAC 1-6-7.1](#) concerning newborn testing in the event of maternal refusal. Repeals [410 IAC 1-7-11](#). Effective 30 days after filing with the Publisher.

[410 IAC 1-6-3](#); [410 IAC 1-6-4](#); [410 IAC 1-6-5](#); [410 IAC 1-6-6](#); [410 IAC 1-6-7](#); [410 IAC 1-6-7.1](#); [410 IAC 1-7-7](#); [410 IAC 1-7-8](#); [410 IAC 1-7-10](#); [410 IAC 1-7-11](#); [410 IAC 1-7-12](#); [410 IAC 1-7-13](#); [410 IAC 1-7-14](#); [410 IAC 1-7-15](#); [410 IAC 1-7-16](#)

SECTION 1. [410 IAC 1-6-3](#) IS AMENDED TO READ AS FOLLOWS:

**[410 IAC 1-6-3](#) "Prenatal care provider" defined****Authority:** [IC 16-19-3-5](#)**Affected:** [IC 25-22.5](#); [IC 25-23](#); [IC 25-27.5](#)

Sec. 3. "Prenatal care provider" means:

- (1) a physician licensed under [IC 25-22.5](#);
- (2) a registered nurse licensed under [IC 25-23](#);
- (3) a licensed practical nurse licensed under [IC 25-23](#); or
- (4) an advanced practice nurse licensed under [IC 25-23](#);
- (5) a midwife licensed under [IC 25-23](#); or**
- (6) a physician assistant licensed under [IC 25-27.5](#);**

who provides prenatal care within the scope of the provider's license.

*(Indiana State Department of Health; [410 IAC 1-6-3](#); filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661; readopted filed Jul 14, 2011, 11:42 a.m.: [20110810-IR-410110253RFA](#); filed May 4, 2012, 10:17 a.m.: [20120530-IR-410110458FRA](#))*

SECTION 2. [410 IAC 1-6-4](#) IS AMENDED TO READ AS FOLLOWS:

**[410 IAC 1-6-4](#) Human immunodeficiency virus information and counseling to a pregnant patient****Authority:** [IC 16-19-3-5](#)**Affected:** [IC 16-41-6](#)

Sec. 4. (a) The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall ~~offer~~ **provide** human immunodeficiency virus (HIV) information and counseling to the pregnant patient. The information and counseling must include the following:

- (1) A description of the methods of ~~human immunodeficiency virus~~ HIV transmission, **including breastfeeding.**
- (2) A discussion of risk reduction behavior modifications, including ~~methods~~ **interventions** to reduce the risk of perinatal transmission.
- (3) Referral information to other ~~human immunodeficiency virus~~ HIV prevention **testing** and psychosocial services. ~~if appropriate, including anonymous and confidential test sites approved by the state department.~~

(b) A group practice, clinic, or hospital shall designate, in writing, a health care professional to implement this rule.

(Indiana State Department of Health; [410 IAC 1-6-4](#); filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661; readopted filed Jul 14, 2011, 11:42 a.m.: [20110810-IR-410110253RFA](#); filed May 4, 2012, 10:17 a.m.: [20120530-IR-410110458FRA](#))

SECTION 3. [410 IAC 1-6-5](#) IS AMENDED TO READ AS FOLLOWS:

**[410 IAC 1-6-5](#) Reasons for not obtaining a human immunodeficiency virus test**

**Authority:** [IC 16-19-3-5](#)

**Affected:** [IC 16-41-6](#)

Sec. 5. The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall ~~offer an~~ **obtain a** human immunodeficiency virus (HIV) test ~~to~~ **from the pregnant** patient unless:

- (1) a positive ~~human immunodeficiency virus~~ HIV test result is already documented in the **pregnant** patient's medical record; or
- (2) the **pregnant** patient:
  - (A) has acquired immune deficiency syndrome (AIDS) as diagnosed by a physician; **or**
  - (B) **refuses in writing an HIV test.**

(Indiana State Department of Health; [410 IAC 1-6-5](#); filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661; readopted filed Jul 14, 2011, 11:42 a.m.: [20110810-IR-410110253RFA](#); filed May 4, 2012, 10:17 a.m.: [20120530-IR-410110458FRA](#))

SECTION 4. [410 IAC 1-6-6](#) IS AMENDED TO READ AS FOLLOWS:

**[410 IAC 1-6-6](#) Human immunodeficiency virus test**

**Authority:** [IC 16-19-3-5](#)

**Affected:** [IC 16-41-6](#)

Sec. 6. (a) In ~~offering an~~ **providing a** human immunodeficiency virus (HIV) test under section 5 of this rule, the prenatal care provider shall discuss the following with the pregnant patient:

- (1) The purpose of the ~~human immunodeficiency virus~~ HIV test.
- (2) The risk and benefits of the ~~human immunodeficiency virus~~ HIV test.
- (3) The voluntary nature of the ~~human immunodeficiency virus (HIV)~~ test **will be performed routinely, unless it is refused in writing.**

(b) If the pregnant patient ~~voluntarily consents to human immunodeficiency virus~~ **presents in labor with no documented HIV testing,** the prenatal care provider shall arrange for human immunodeficiency virus (HIV) testing directly or by referral, including referral to anonymous and confidential test sites approved by the department. **test on record, then a rapid test must be administered.**

(Indiana State Department of Health; [410 IAC 1-6-6](#); filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661; readopted filed Jul 14, 2011, 11:42 a.m.: [20110810-IR-410110253RFA](#); filed May 4, 2012, 10:17 a.m.: [20120530-IR-410110458FRA](#))

SECTION 5. [410 IAC 1-6-7](#) IS AMENDED TO READ AS FOLLOWS:

**[410 IAC 1-6-7](#) Documentation**

**Authority:** [IC 16-19-3-5](#); [IC 16-41-6-11](#)

**Affected:** [IC 16-41-6](#)

Sec. 7. (a) The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall document in the **pregnant** patient's medical record that the prenatal care provider ~~offered~~ **provided** the following to the **pregnant** patient:

- (1) **Information and counseling regarding human immunodeficiency virus (HIV) information and counseling and the standard licensed diagnostic test for HIV.**
- (2) An human immunodeficiency virus HIV test.

~~(b) Documentation in the patient's medical record must include notation that the following was offered to the patient:~~

- ~~(1) A description of the methods of human immunodeficiency virus (HIV) transmission.~~
- ~~(2) A discussion of risk reduction behavior modifications, including methods to reduce the risk of perinatal transmission.~~
- ~~(3) Referral information to other human immunodeficiency virus (HIV) prevention and psychosocial services, if appropriate, including anonymous and confidential test sites approved by the department.~~
- ~~(4) Discussion of the purpose of the human immunodeficiency virus (HIV) test.~~
- ~~(5) Discussion of the risk and benefits of the human immunodeficiency virus (HIV) test.~~
- ~~(6) Discussion of the voluntary nature of the human immunodeficiency virus (HIV) test.~~
- ~~(7) Documentation that the patient understood the information offered.~~

~~(e) (b) Signature by the patient on a form provided by the department, or one which is substantially similar, acknowledging that she has been provided and has read, or, if unable to read and understand, has had the contents of the document read and explained to her by her prenatal care provider to her satisfaction, complies with the requirements of this section. with the items described in subsection (a) is not necessary.~~

**(c) The person who completes a certificate of live birth must document the following on the confidential part of each birth certificate:**

- (1) Whether a standard licensed diagnostic test for HIV was performed on the woman who bore the child.**
- (2) If a standard licensed diagnostic test for HIV was performed:**
  - (A) the date the blood specimen was taken; and**
  - (B) whether the test was performed during pregnancy or at the time of delivery.**
- (3) If a standard licensed diagnostic test for HIV was not performed, the reason the test was not performed.**

*(Indiana State Department of Health; [410 IAC 1-6-7](#); filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971; readopted filed Jul 15, 2005, 8:00 a.m.: 28 IR 3661; readopted filed Jul 14, 2011, 11:42 a.m.: [20110810-IR-410110253RFA](#); filed May 4, 2012, 10:17 a.m.: [20120530-IR-410110458FRA](#))*

SECTION 6. [410 IAC 1-6-7.1](#) IS ADDED TO READ AS FOLLOWS:

**[410 IAC 1-6-7.1](#) Newborn testing in the event of maternal refusal**

**Authority:** [IC 16-41-6-11](#)

**Affected:** [IC 16-41-6-4](#)

**Sec. 7.1. If the woman who bore the child has not had a test performed for human immunodeficiency virus (HIV) or if the mother has refused a test for the newborn infant to detect HIV or the antibody or antigen to HIV and a physician believes that testing the newborn infant is medically necessary, the physician overseeing the care of the newborn infant may order a confidential test for the newborn infant in order to detect HIV under [IC 16-41-6-4](#). The test must be ordered at the earliest feasible time not exceeding forty-eight (48) hours after the birth of the infant. The mother shall be notified of the test and the result of the test.**

*(Indiana State Department of Health; [410 IAC 1-6-7.1](#); filed May 4, 2012, 10:17 a.m.: [20120530-IR-410110458FRA](#))*

SECTION 7. [410 IAC 1-7-7](#) IS AMENDED TO READ AS FOLLOWS:

**Rule 7. HIV Counseling and Testing of Pregnant Patients**

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**410 IAC 1-7-7 Provider's responsibilities to pregnant patient who has been tested for HIV**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6

Sec. 7. (a) A provider, or ~~his or her~~ **provider's** designee, must ~~do the following:~~ (1) deliver the test results for HIV infected and HIV uninfected **pregnant patients as follows:**

- (1) In a direct, straightforward, and confidential manner.
- (2) ~~Deliver the results~~ At the earliest possible encounter after testing.
- (3) ~~Deliver the results~~ Face-to-face for HIV infected **pregnant patients.**

(b) If the test results positive, the treating provider, or ~~his or her~~ **provider's** designee, must do the following:

- (1) Explain the side effects of any treatment for HIV in a direct, straightforward, confidential manner.
- (2) Discuss pros and cons of initiation of drug therapy, **including reducing the risk of perinatal transmission significantly.**

(3) Discuss treatment recommendations based on the U.S. Public Health Service Task Force recommendation for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States in MMWR 51, RR-18.

(4) **Comply with reporting requirements to the local health officer under 410 IAC 1-2.3-47 regarding an HIV-infected pregnant woman or perinatally exposed infant.**

*(Indiana State Department of Health; 410 IAC 1-7-7; filed Jun 25, 2004, 11:05 a.m.: 27 IR 3496; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA; filed May 4, 2012, 10:17 a.m.: 20120530-IR-410110458FRA)*

SECTION 8. 410 IAC 1-7-8 IS AMENDED TO READ AS FOLLOWS:

**410 IAC 1-7-8 Pregnant patient on a waiting list for HIV medical services**

**Authority:** IC 16-41-6-11

**Affected:** IC 16-41-6-5; IC 16-41-6-6

Sec. 8. (a) A pregnant ~~woman~~ **patient** must have a complete application for the HIV medical services program on file with the department.

(b) A pregnant ~~woman~~ **patient** who meets all the qualifications to participate in the HIV medical services program and tests positive under IC 16-41-6-5 or IC 16-41-6-6 shall be given first priority on a waiting list for the program if a waiting list exists for the HIV medical services program.

(c) A pregnant ~~woman~~ **patient** who tests positive under IC 16-41-6-5 or IC 16-41-6-6 may appeal her placement on a waiting list for HIV medical services by filing a written appeal with the department.

(d) The appeal shall be filed within fifteen (15) days of receipt of the notification of placement on a waiting list.

(e) The appeal will be reviewed by the state health commissioner, or ~~his or her~~ **the commissioner's** designee, who will also make the determination in the case within seventy-two (72) hours of receipt of all requested medical information and other pertinent documentation, as detailed by section 9 of this rule, necessary to determine the applicant's eligibility for services.

(f) The appeal must include name, date of birth, and mailing address **of the pregnant patient.**

*(Indiana State Department of Health; 410 IAC 1-7-8; filed Jun 25, 2004, 11:05 a.m.: 27 IR 3496; readopted filed Jul 15, 2010, 12:12 p.m.: 20100728-IR-410100261RFA; filed May 4, 2012, 10:17 a.m.: 20120530-IR-410110458FRA)*

SECTION 9. 410 IAC 1-7-10 IS AMENDED TO READ AS FOLLOWS:

**410 IAC 1-7-10 Information to the HIV-positive pregnant patient**

**Authority:** [IC 16-41-6-11](#)

**Affected:** [IC 16-41-6](#)

Sec. 10. (a) A provider, or his or her **provider's** designee, shall provide the following to a pregnant ~~women~~ **patient** at the appropriate times, which could include before delivery, at delivery, and after delivery:

- (1) An explanation of the nature of AIDS and HIV, which
  - ~~(A) is consistent with MMWR 41, RR-17, and MMWR 43, RR12. and~~
  - ~~(B) includes the following elements:~~
    - ~~(i) HIV results in a defect in cell-mediated immune response causing increased susceptibility to opportunistic infections and certain rare cancers.~~
    - ~~(ii) HIV is a virus that is transmitted from one (1) person to another through blood, semen, vaginal secretions, or breast milk.~~
    - ~~(iii) HIV is a virus that, without treatment, aggressively destroys the immune system.~~
    - ~~(iv) AIDS is a severe immunological disorder that can result from HIV.~~
- (2) Information that it is unlawful to discriminate against persons living with HIV in areas of employment, housing, and provision of health care services. If the ~~women~~ **patients** believe that they have been discriminated against, they may contact the Indiana civil rights commission.
- (3) Information that ~~women~~ **patients** who have tested positive for HIV or who have been diagnosed with AIDS are not to engage in high-risk activity (including sexual or needle-sharing contact, which has been demonstrated to transmit a dangerous communicable disease) without warning past, present, or future sexual or needle-sharing partners before engaging in that high-risk activity. Carriers who know of their status as a carrier of HIV or AIDS have a duty to warn or cause to be warned by a third party a person at risk, including a spouse of the last ten (10) years, of the following:
  - (A) The carrier's disease status.
  - (B) The need to seek health care, such as counseling and testing.
- (4) Information about risk behaviors for HIV transmission that is consistent with MMWR 50, RR19. It must include the following:
  - (A) High-risk activities refer to sexual or needle-sharing contact, which has been demonstrated to transmit HIV.
  - (B) HIV is known to be transmitted through **the following**:
    - (i) Blood.**
    - (ii) Semen.**
    - (iii) Vaginal secretions. and**
    - (iv) Breast milk.**
- (5) Information about the risk of transmission through breastfeeding that is consistent with MMWR 50, RR19, including that breastfeeding by an HIV positive ~~woman~~ **patient** carries a risk for transmission of the virus from mother to infant.
- (6) Referral information to other HIV prevention testing and psychosocial services, if appropriate.**

(b) The department will continue to be a resource for educational information and referral sources.

(Indiana State Department of Health; [410 IAC 1-7-10](#); filed Jun 25, 2004, 11:05 a.m.: 27 IR 3497; readopted filed Jul 15, 2010, 12:12 p.m.: [20100728-IR-410100261RFA](#); filed May 4, 2012, 10:17 a.m.: [20120530-IR-410110458FRA](#))

SECTION 10. [410 IAC 1-7-12](#) IS AMENDED TO READ AS FOLLOWS:

**410 IAC 1-7-12 Obtaining consent**

**Authority:** [IC 16-41-6-11](#)

**Affected:** [IC 16-41-6-7](#); [IC 16-41-6-8](#)

Sec. 12. (a) The provider shall **do the following**:

- (1) Follow the procedures for obtaining consent of the ~~woman~~ pregnant patient as detailed in [IC 16-41-6-2](#). [IC 16-41-6-8](#).**
- ~~(b) The provider shall~~ **(2) Inform the ~~woman~~ pregnant patient of her options under [IC 16-41-6-7](#).**

(Indiana State Department of Health; [410 IAC 1-7-12](#); filed Jun 25, 2004, 11:05 a.m.: 27 IR 3497; readopted filed Jul 15, 2010, 12:12 p.m.: [20100728-IR-410100261RFA](#); filed May 4, 2012, 10:17 a.m.: [20120530-IR-410110458FRA](#))

SECTION 11. [410 IAC 1-7-13](#) IS AMENDED TO READ AS FOLLOWS:

**[410 IAC 1-7-13](#) Post-test counseling procedures**

Authority: [IC 16-41-6-11](#)

Affected: [IC 16-41-6](#)

Sec. 13. Post-test counseling will be conducted in a direct, straightforward, confidential manner by the provider or his or her **the provider's** designee.

(Indiana State Department of Health; [410 IAC 1-7-13](#); filed Jun 25, 2004, 11:05 a.m.: 27 IR 3498; readopted filed Jul 15, 2010, 12:12 p.m.: [20100728-IR-410100261RFA](#); filed May 4, 2012, 10:17 a.m.: [20120530-IR-410110458FRA](#))

SECTION 12. [410 IAC 1-7-14](#) IS AMENDED TO READ AS FOLLOWS:

**[410 IAC 1-7-14](#) Referral procedures**

Authority: [IC 16-41-6-11](#)

Affected: [IC 16-41-6](#)

Sec. 14. The provider shall assess the **pregnant** patient's level of need and provide referrals to the appropriate services, which may include HIV-specific case management services.

(Indiana State Department of Health; [410 IAC 1-7-14](#); filed Jun 25, 2004, 11:05 a.m.: 27 IR 3498; readopted filed Jul 15, 2010, 12:12 p.m.: [20100728-IR-410100261RFA](#); filed May 4, 2012, 10:17 a.m.: [20120530-IR-410110458FRA](#))

SECTION 13. [410 IAC 1-7-15](#) IS AMENDED TO READ AS FOLLOWS:

**[410 IAC 1-7-15](#) Importance of immediate HIV medical care**

Authority: [IC 16-41-6-11](#)

Affected: [IC 16-41-6](#)

Sec. 15. Providers, or their designees, shall counsel the **pregnant** patient regarding the importance of immediate entry into medical care for the duration of the pregnancy.

(Indiana State Department of Health; [410 IAC 1-7-15](#); filed Jun 25, 2004, 11:05 a.m.: 27 IR 3498; readopted filed Jul 15, 2010, 12:12 p.m.: [20100728-IR-410100261RFA](#); filed May 4, 2012, 10:17 a.m.: [20120530-IR-410110458FRA](#))

SECTION 14. [410 IAC 1-7-16](#) IS AMENDED TO READ AS FOLLOWS:

**[410 IAC 1-7-16](#) Explanation of decreasing transmission of HIV during pregnancy**

Authority: [IC 16-41-6-11](#)

Affected: [IC 16-41-6](#)

Sec. 16. (a) Providers shall counsel that HIV can be transmitted to the fetus during pregnancy and treatment can significantly decrease that transmission.

(b) Providers shall counsel, prior to delivery, that giving birth by cesarean section may decrease transmission of HIV to the child, especially when done in combination with medications, if the HIV test results are positive.

(c) Counseling on this matter shall be conducted in a direct, straightforward, confidential manner by the provider or ~~his or her~~ **the provider's** designee.

(Indiana State Department of Health; [410 IAC 1-7-16](#); filed Jun 25, 2004, 11:05 a.m.: 27 IR 3498; readopted filed Jul 15, 2010, 12:12 p.m.: [20100728-IR-410100261RFA](#); filed May 4, 2012, 10:17 a.m.: [20120530-IR-410110458FRA](#))

SECTION 15. [410 IAC 1-7-11](#) IS REPEALED.

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Small Business Regulatory Coordinator: Kimberly Crawford, Indiana State Department of Health, 2 North Meridian Street, 3H-99, Indianapolis, IN 46204, (317) 233-7874, [kicrawford@isdh.in.gov](mailto:kicrawford@isdh.in.gov)

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